UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA – EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL TREATMENT CENTER, INC., et al.

Defendants.

Case No.
EDCV 18-1005 JGB (KKx)

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This is a statutory injunction proceeding in which the United States, on behalf of the U.S. Food and Drug Administration ("FDA"), seeks to permanently enjoin Defendants California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, and Drs. Elliot B. Lander, M.D., and Mark Berman, M.D., from performing various stem cell treatments on patients. The United States alleges these treatments violate the Federal Food, Drug, and Cosmetic Act ("FDCA"). Specifically, the United States alleges that three of Defendants' stromal vascular stem cell treatments violate: 21 U.S.C. § 331(k) by causing the adulteration of drugs; 21 U.S.C. § 331(k) by causing the misbranding of drugs; and 21 U.S.C. § 331(c) by receiving drugs that are misbranded.

The case was tried to the Court on May 4, 5, 6, 7, 11, 12, and 13, 2021. Oral closing arguments occurred on August 20, 2021. Because of the ongoing Covid-19 pandemic, the United States appeared via videoconference. At the August 20, 2021 closing arguments, the Court ordered supplemental briefing, which was submitted by both sides on August 27, 2021, and September 1, 2021. ("Pl's Supp Br.," Dkt. No. 179; "Defs Supp Br.," Dkt. No. 178; "Pl's Supp Opp.," Dkt. No. 181; "Defs Supp Opp.," Dkt. No. 180.)

The Court, having considered all the evidence presented by the parties, the written submissions from both sides, and the argument of counsel, issues the following Findings of Fact and Conclusions of Law.

I. FINDINGS OF FACT

A. General Facts

1. Defendant California Stem Cell Treatment Center ("CSCTC") is a California professional corporation founded in 2010, with its principal place of business located at 72-780 Country Club Drive, Suite 301, Rancho Mirage, California 92270 ("CSCTC Rancho Mirage"). California Stem Cell

Treatment Center has a second location at 120 South Spalding Drive, Suite 300, Beverly Hills, California 90212 ("CSCTC Beverly Hills."). ("Stip. Facts," Dkt. No. 113-1 ¶ 1.)

2. Defendant Elliot B. Lander, M.D., a surgeon and board-certified urologist, is the co-owner and Co-Medical Director of CSCTC. He is the most responsible individual at CSCTC Rancho Mirage and performs his duties there, within the jurisdiction of this Court. He manages all firm employees at CSCTC Rancho Mirage. ("Pl. SOF," Dkt. No. 169-1 ¶ 3.)
3. Defendant Mark Berman, M.D., a board-certified cosmetic surgeon, is the co-owner and Co-Medical Director of CSCTC.[1] He performs his duties at the CSCTC Beverly Hills facility, within the jurisdiction of this Court. He is the most responsible individual at CSCTC Beverly Hills. (Id. ¶ 4.)
4. Defendant Cell Surgical Network Corporation ("CSN") is a California corporation founded and owned by Dr. Berman and Dr. Lander that is registered to do business at 72-780 Country Club Drive, Suite 301, Rancho Mirage, California 92270, the same address as CSCTC Rancho Mirage. (Stip. Facts ¶ 2.)
5. CSN operates a one-employee warehouse in Palm Desert, California, from which equipment and supplies are shipped to CSN affiliates. (Id. ¶ 3.)
6. Drs. Berman and Lander are the co-owners and Co-Medical Directors of CSN. They are also the co-owners of Cells On Ice, Inc., which has assisted in the recovery of adipose tissue sent outside of the State of California. (Pl. SOF ¶ 6.)

B. The "SVF Surgical Procedure"

[1] There have been news accounts of Mr. Berman's death in May 2022. The parties have not filed a judicially noticeable document verifying the accounts. The Court's Findings of Fact are written in light of the lack of verification.

7. Defendants offer patients a treatment called the "SVF Surgical Procedure." In this procedure, a licensed physician targets stromal vascular fraction cells ("SVF Cells") for extraction and then implants those same cells that were removed back into the same patient during the same procedure. ("Defs. SOF," Dkt. No. 168-1 ¶ 1.)
8. SVF Cells are comprised of multiple cell types found within adipose tissue; these include mesenchymal stem cells ("MSC Cells"), hematopoietic cells, early (progenitors) and mature lineage stages of endothelia, pericyte progenitor cells (also called perivascular cells), red blood cells, white blood cells, lymphocytes, and fibroblasts among other cells. SVF Cells are the naturally occurring part of the adipose tissue that does not contain the adipocytes (fat cells). (Id. ¶ 2.)
9. Surgeons routinely work on both tissues and cells that make up tissues. Surgery universally involves dissection (cutting and separation) of tissues through mechanical or chemical means, and has evolved to where surgeons can isolate cells following removal from a patient's body. Dissected tissues and cells that have been isolated can be surgically relocated and re-purposed to other parts of a patient's body. (Id. ¶ 4.)
10. Surgery is intended for the treatment and prevention of disease in the human body. It can treat chronic and systemic conditions, and it is intended to affect the structure or function of the human body. There are no FDA-approved or disapproved surgical procedures. (Id. ¶¶ 5-8.)
11. Accordingly, the surgical treatments at issue here have not been licensed or approved by the United States Food and Drug Administration. There are not now, nor have there ever been, any approved new drug applications for the surgical treatments ("NDAs") filed with FDA pursuant to 21 U.S.C. § 355(b) or (j). And there are not now, nor have there ever been any approved

biologics license applications ("BLAs") filed with FDA pursuant to 42 U.S.C. § 262 for the treatments. (Stip. Facts ¶¶ 7-9.)

12. The SVF Surgical Procedure targets for removal mesenchymal stem cells and the hemopoietic or angiogenic stem cells located within the adipose tissue, not the adipose tissue itself. (Defs. SOF ¶ 10.)

13. The SVF Surgical Procedure involves collecting the patient's SVF Cells naturally contained in the patient's adipose tissue and relocating those SVF Cells back into the same patient. The SVF Cells are already in circulation within the body. The SVF Surgical Procedure increases the number of available SVF Cells in circulation or around an injured area. (Id. ¶ 11.)

14. The entire SVF Surgical Procedure, including the extraction, isolation, and reimplantation of SVF Cells occurs in California during a single, outpatient procedure at a surgical clinic. (Id. ¶ 12.)

15. During the SVF Surgical Procedure, a licensed physician collects the patient's SVF Cells using a technique called "mini-liposuction via subdermal local anesthesia," which permits the liposuction of the SVF Cells, along with the adipose and connective tissue that contains the SVF Cells, under local anesthesia. Many cells are mechanically separated ("mechanical cutting") from the adipose tissue during the liposuction procedure, as is common in all surgeries. Next, the removed adipose tissue is centrifuged to remove the anesthesia and to further mechanically dissociate the SVF Cells from the adipose tissue. The physician then uses surgical tools—namely, Liberase enzymes and a centrifuge device—to isolate the SVF Cells from adipocytes (fat cells). Finally, the SVF Cells are filtered through a hundred micron filter and viewed through a special micrograph to ensure that the SVF Cells are free-floating, round, and do not contain clumps of particles or debris. The SVF Cells are then suspended in a sterile saline solution, after which they are relocated back into the patient's body. Saline is a benign

crystalloid, widely used in the practice of medicine. No new product is created by the use of saline as a delivery mechanism. (Id. ¶¶ 13-15, 21-22.)

16. All of the materials used to isolate SVF Cells during the SVF Surgical Procedure are FDA-approved drugs or FDA-cleared devices. (Id. ¶ 17.)

17. The SVF Cells are not altered, chemically or biologically, at any point during the SVF Surgical Procedure. There are no genes added to or removed from the SVF Cells during the SVF Surgical Procedure. The SVF Surgical Procedure does not change the size or genetic makeup of the SVF Cells. The procedure does not alter the biological characteristics of the SVF cells, nor does it affect their ability to proliferate. (Id. ¶¶ 23-24.)

18. The SVF Surgical Procedure does not create any new material or introduce any foreign article into the body. Unlike manufactured drugs, the SVF Surgical Procedure does not create any cellular or tissue-based product that did not previously exist within the patient. (Id. ¶¶ 44.)

19. Drs. Berman and Lander are board certified surgeons. Drs. Berman and Lander and their practices are regulated by the State of California Medical Board. Dr. Berman's facility in Beverly Hills is accredited by the Accreditation Association for Ambulatory Health Care ("AAAHC") per California law. The operating rooms in which Drs. Berman and Lander perform the SVF Surgical Procedure comply with all health and safety standards established by the California State Medical Board for outpatient procedures. (Id. ¶¶ 51-52.)

C. The "Expanded MSC Surgical Procedure"

20. In addition to the SVF Surgical Procedure, Drs. Berman and Lander perform a procedure whereby a patient's adipose tissue is removed and sent to a GMP-compliant tissue bank to isolate MSC Cells. The MSC Cells are then replicated and stored until the same patients request that they be

returned for implantation into her body (the "Expanded MSC Surgical Procedure"). (Id. ¶ 61.)

21. During the Expanded MSC Surgical Procedure, a qualified candidate undergoes liposuction at either Dr. Berman or Dr. Lander's medical facilities. Drs. Berman and Lander do not perform the remainder of the SVF Surgical Procedure on the harvested adipose tissue but send the tissue to a GMP-compliant third party. (Id. ¶ 62.)

22. A patient is eligible for the Expanded MSC Surgical Procedure where the individual has a medical condition that will require multiple treatments, but the individual is unable or unwilling to undergo multiple liposuctions. (Id. ¶ 63.)

23. Drs. Berman and Lander do not adulterate, manufacture, process or store the patient's adipose tissue during the Expanded MSC Surgical Procedure. The third party isolates the MSC Cells from the adipose tissue using a technique that is similar to the SVF Surgical Procedure. The third party then places the MSC Cells in a culture, in which the MSC Cells naturally begin to replicate (i.e., expand in number), thereby creating a sufficient number of cells under GMP conditions for multiple treatments (the "Expanded MSC Cells"). Replication or propagation is a natural state for stem cells and the Expanded MSC Cells retain all of the biological characteristics of the MSC Cells. The Expanded MSC Cells retain their cell markers, and do not differentiate while in the culture or during storage. The third-party tissue bank places the Expanded MSC Cells into a sterile vial labeled with the patient's name, date, and description pursuant to well-defined patient identifier protocols. The third-party tissue bank places the Expanded MSC Cells into a sterile vial labeled with the patient's name, date, and description pursuant to well-defined patient identifier protocols. (Id. ¶¶ 64-69.)

24. The Expanded MSC Cells are intended for autologous use, which refers to the "implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered." See 21 C.F.R. § 1271.3(a).

25. Defendants can (and do) administer the Expanded MSC Cells weeks, months, and even years after the patient's adipose tissue is removed. ("US SOF," Dkt. No. 169-1 ¶ 22.)

26. At the time of the inspection in 2017, Drs. Berman and Lander were sending the adipose tissue to American Cryostem ("ACS") for isolation of the MSC Cells and storage of the same. (Defs. SOF ¶ 71.)

27. Drs. Berman and Lander believed that ACS was a GMP facility based on ACS's representations. Drs. Berman and Lander ceased utilizing ACS in connection with the Expanded MSC Surgical Procedure following notice from the FDA that ACS was not complying with GMP regulations. (Id. ¶ 72.)

28. The third party that Drs. Berman and Lander currently use is registered with the FDA and has been inspected by the FDA, with no resulting deficiency letters. (Id. ¶ 73.)

29. The Government did not present any evidence that Defendants are adulterating any material in connection with the Expanded MSC Surgical Procedure. (Id. ¶ 79.)

30. Only licensed practitioners can perform the Expanded MSC Surgical Procedure. (Id. ¶ 80.)

31. At all times, the vials containing the Expanded MSC Cells are labeled with the patient's name, date, and description pursuant to patient identifier protocols. (Id. ¶ 82.)

32. The Government did not present any evidence that Defendants label or mislabel any material regulated by the FDA in connection with the Expanded

MSC Surgical Procedure. Nor did it present any evidence regarding the labeling Defendants receive from any GMP facility in connection with the Expanded MSC Surgical Procedure, or that any such labeling is deficient. (Id. ¶¶ 83-84.)

33. Drs. Berman and Lander do not charge for the Expanded MSC Cells; they only charge a surgical fee for the liposuction procedure. Patients paid a separate facility fee to the third party for the banking or storage of the Expanded MSC Cells. (Id. ¶¶ 85-86.)

D. The "SVF/ACAM2000 Treatment"

34. Drs. Berman and Lander partnered with StemImmune to study the safety of utilizing SVF Cells as a mechanism to deliver ACAM2000, an oncolytic virus, to cancer cells ("SVF/ACAM2000 Treatment"). (Id. ¶ 87.)

35. The SVF/ACAM2000 Treatment was a limited experimental treatment only available to individuals with terminal cancer for whom traditional treatment had failed. Drs. Berman and Lander would prepare the SVF Cells using their standard method, then add the ACAM2000 to the SVF Cells ACAM2000 ("SVF/ACAM2000 Cells"), before deploying into the same patient's body. (Id. ¶ 88.)

36. The combination of SVF and ACAM2000 Cells is a manufactured product. (Pls. SOF ¶ 160.)

37. ACAM2000 is an FDA-approved vaccine. (Defs. SOF ¶ 89.)

38. The federal government maintains exclusive control over ACAM2000 as part of the country's Strategic National Stockpile and it may only be distributed by specific government agencies. It is not publicly available, but researchers may request vials for studies. (Id. ¶ 91.)

39. Drs. Berman and Lander cannot perform the SVF/ACAM2000 Treatment without access to ACAM2000. (Id. ¶ 92.)

40. The FDA confiscated vials of ACAM2000 from StemImmune's laboratories at the University of California, San Diego in August 2017. Dr. Berman last performed the SVF/ACAM2000 Treatment before the FDA's 2017 confiscation. Dr. Lander last performed the SVF/ACAM2000 Treatment in June 2016. Drs. Berman and Lander have no desire or intention to perform the SVF/ACAM2000 Treatment outside of proper FDA regulatory approval or a determination that that SVF/ACAM2000 Cells are not a drug and do not fall under FDCA regulations. (Id. ¶ 94-97.)

41. The ACAM2000 that Defendants used for the SVF/ACAM2000 Surgical Procedure was shipped in interstate commerce from the Centers for Disease Control ("CDC") in Georgia. (Pls. SOF ¶ 173.)

42. The SVF/ACAM2000 Cells were not placed in any container for preservation, storage, or later use. (Defs. SOF ¶ 102.)

43. The SVF/ACAM2000 Treatment was performed at all times by Drs. Berman and Lander, who are licensed physicians. Drs. Berman and Lander performed the SVF/ACAM2000 Treatment pursuant to the IRB-approved study protocols, which included detailed step-by-step instructions on how to extract and isolate the SVF Cells, reconstitute the ACAM2000 vaccine, and implant the SVF/ACAM2000 Cells. (Id. ¶ 103.)

II. CONCLUSIONS OF LAW

A. General

1. The Federal Food, Drug, and Cosmetic Act ("FDCA") defines a drug as any "article," or component thereof, that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or is "intended to affect the structure or any function of the body of man or other animals." See 21 U.S.C. § 321(g)(1)(B), (C), and (D). However, surgical procedures—standard in the practice of medicine—are also intended for the

diagnosis, cure, mitigation, treatment, or prevention of disease. When passing the FDCA, Congress explicitly rejected any attempt to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Indeed, Congress recognized the limitations of the FDA and rejected "any intent to directly regulate the practice of medicine." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 351 n.5 (2001).

2. The line between "drug" and "procedure" is especially muddy when licensed medical doctors enter a patient's body, extract that patient's cells, and reintroduce those cells to that patient after some amount of cellular processing. The United States argues that this scenario constitutes the production of FDCA drugs. Defendants argue that this is mere surgery, the exclusive province of the medical practitioners, and not something which the FDCA may regulate.
3. The Court concludes that neither Defendants' SVF Surgical Procedure nor its Expanded MSC Procedure are "drugs" within the meaning of the FDCA. In contrast, Defendants' SVF/ACAM2000 Treatment involves the creation of a drug under the FDCA.
4. Accordingly, the SVF Procedure and Expanded MSC Procedure are not subject to the FDCA's adulteration and misbranding provisions. See 21 U.S.C. §§ 351, 352; 21 C.F.R. § 1271.20; Final Rule Concerning Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447, 5449 and 5456 (Jan. 19, 2001) (to be codified at 21 C.F.R. Part 1270).
5. Neither the SVF Procedure nor the Expanded MSC Procedure involves creating "prescription drugs" within the meaning of 21 U.S.C. §

353(b)(1)(A), nor does it involve creating "new drugs" within the meaning of 21 U.S.C. § 321(p).

6. Additionally, Defendants' SVF Procedure—but not the Expanded MSC Procedure—also qualifies for the Same Surgical Procedure Exception. The SSP Exception exempts from FDA oversight any "establishment that removes HCT/Ps from an individual and implants such HCT/Ps into the same individual during the same surgical procedure." 21 C.F.R. § 1271.15.

7. "HCT/Ps" is an acronym for "[h]uman cells, tissues, or cellular or tissue-based products," and HCT/Ps are defined in Section 1271.3(d) as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d).

8. "Construction which gives effect to all of the words of a statute or regulation is preferred over an interpretation which renders some of the statute or regulation ineffective." First Charter Financial Corp. v. United States, 669 F.2d 1342, 1350 (9th Cir. 1982) (internal citation omitted). The definition of HCT/Ps specifies that HCT/Ps are "articles containing **or** consisting of human cells or tissues," in the disjunctive, indicating that articles containing and articles consisting of human cells or tissues may be two different things. 21 C.F.R. § 1271.3(d) (emphasis added). The adipose tissue Defendants remove from patients clearly consists of human cells. And whatever is injected back into patients as part of Defendants' SVF Surgical Procedure and Expanded MSC Surgical Procedure certainly contains such cells.

9. Most critically, the definition of HCT/Ps states that HCT/Ps are "articles . . . **intended for** implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d) (emphasis added). The cellular products Defendants create in the course of all procedures at issue here are clearly intended for transfer back into human recipients.

10. Accordingly, SVF Cells removed from patients as part of Defendants' procedures are HCT/Ps. The adipose tissue Defendants remove from patients to produce their CSCTC products is an HCT/P. 21 C.F.R. § 1271.3(d).

11. Because the entire SVF Surgical Procedure, including the extraction, isolation, and reimplantation of SVF Cells occurs during a single, outpatient procedure at a surgical clinic, Defendants' SVF Surgical Procedure involves introducing HCT/Ps back into patients during the "same surgical procedure," as they were extracted, triggering the SSP exception. 21 C.F.R. § 1271.15(b). The same is not true of the Expanded MSC Procedure. Though the cells extracted for both the SVF Surgical Procedure and the Expanded MSC Procedure are HCT/Ps, only the SVF Surgical Procedure qualifies for the SSP Exception.

B. The SVF Surgical Procedure

12. For Claim One, the Government must prove: (1) that the SVF Surgical Procedure involves a drug, (2) that the SVF Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) that the methods used in, or the facilities or controls used for, the manufacture of the drug are not in conformity with current Good Manufacturing Practices ("cGMP"). 21 U.S.C. §§ 331(k), 352(a)(2)(B).

13. For Claim Two, the Government must prove: (1) that the SVF Surgical Procedure involves a drug, (2) that the SVF Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) that it does not contain adequate directions for use or the symbol "Rx." 21 U.S.C. §§ 352(f), 352(b)(2).

14. The Same Surgical Procedure Exception ("SSP Exception") is a complete defense to Claims One and Two, and Defendants have established that the SSP Exception applies to the SVF Surgical Procedure.

15. Additionally and alternatively, the Government failed to carry its burden because the SVF Surgical Procedure is not a drug.

16. In evaluating whether the SVF Surgical Procedure satisfies the requirements of the SSP Exception, the appropriate focus is on the SVF Cells. The SSP Exception unambiguously states that the focus is on the target of the removal—either the cell or the tissue—rather than the largest system removed. This is the only permissible interpretation of the SSP Exception, which explicitly includes both "tissues" and/or "cells," through its use of the term "HCT/Ps." See 21 C.F.R. §§ 1271.3(d); 1271.15(b). Cells can only be removed from a patient along with larger systems, such as the tissues or organs that they comprise. Focusing on the "tissue" removed while ignoring the target "cells" would eliminate the word "cells" from HCT/Ps and violate the canons of statutory construction.

17. The SVF Surgical Procedure is autologous because it involves collecting a patient's cell population naturally occurring in the patient's adipose tissue and relocating that cell population back into the same patient.

18. The SSP Exception does not have any requirement that the HCT/Ps be unaltered before reinsertion into the patient. See 21 C.F.R. § 1271.15(b). Any reference to whether the HCT/Ps are manipulated and/or altered are located in a different, inapplicable, regulation 21 C.F.R. § 1271.10 (discussing "minimal manipulation").

19. Regardless, the SVF Surgical Procedure does not alter the biological characteristics of the SVF Cells and those cells remain "such HCT/P" that were removed from the patient. There is no evidence that the cells are anything other than autologous cells removed from, belonging to, and returned back to the patient.

20. The GMP-grade Liberase enzyme used by Defendants does not affect ability of the SVF Cells to differentiate. When Liberase is used on SVF Cells, their

cell surface marker expression remains similar, and their viability does not significantly change.

21. The Court finds that Dr. Berman and Dr. Lander are well qualified to opine and testify on the practice of medicine, development of surgical procedures, the SVF Surgical Procedure, and the effect of Liberase on the SVF Cells. The Court finds Defendants' evidence and testimony more credible than Dr. Yong given her failure to analyze the appropriate enzyme. Further, Defendants have actually tested the product at issue (as published in a peer-reviewed journal), while the Government has never collected a sample or tested the SVF Cells or Liberase.

22. In conclusion, the SSP Exception applies to the SVF Surgical Procedure and is a complete defense to Claims One and Two. Because the SSP Exception applies to the SVF Surgical Procedure, Defendants do not fall under FDA jurisdiction and are not governed by the FDCA or associated regulations; therefore, the Government is not entitled to injunctive relief against Defendants.

23. Further, the SSP Exception is unambiguous, thus there is no need for deference to the FDA's interpretation. See Kisor v. Wilkie, 139 S. Ct. 2400, 2414 (2019) ("[T]he possibility of deference can arise only if a regulation is genuinely ambiguous."); Christensen v. Harris Cnty., 529 US 576, 588 (2000) ("The regulation in this case, however, is not ambiguous . . . . To defer to the agency's position would be to permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation.").

24. The SSP Exception does not require that the surgeon implant everything that was removed—including the removed blood and excess artery—for it to apply. The SSP Exception Guidance expressly recognizes that processing steps such as "rinsing [and] cleansing" or "sizing and shaping," including "dilation," "cutting," "meshing," of HCT/Ps do not take a procedure out

of the SSP Exception. See Food & Drug Admin., Regulatory Considerations.

25. Drs. Berman and Lander may lawfully use FDA-cleared medical devices and FDA-approved pharmaceuticals in any manner that they determine is best to care for and treat their patients. Each step of the SVF Surgical Procedure uses FDA-cleared and/or approved medical devices and pharmaceuticals. See 21 U.S.C. § 396.

C. The Expanded MSC Surgical Procedure

26. For Claim Three, the Government must prove: (1) that the Expanded MSC Surgical Procedure involves a drug, (2) that the Expanded MSC Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) that the methods used in, or the facilities or controls used for, the manufacture of the drug are not in conformity with current Good Manufacturing Practices ("cGMP"). 21 U.S.C. §§ 331(k), 352(a)(2)(B).

27. For Claim Four, the Government must prove: (1) that the Expanded MSC Surgical Procedure involves a drug, (2) that the Expanded MSC Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) that it does not contain adequate directions for use of the symbol "Rx." 21 U.S.C. §§ 352(f), 352(b)(2).

28. For Claim Five, the Government must prove: (1) that the Expanded MSC Surgical Procedure involves a drug, (2) that the Expanded MSC Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) Defendants received a misbranded drug for pay or otherwise.

29. As a threshold matter, the cells involved in the Expanded MSC Surgical Procedure are not drugs. They are human cells removed from patients and then reintroduced into those same patients. They are not fungible goods that can be sold, mass produced, or patented. See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013) (holding that naturally-

occurring human body parts that are a "product of nature and not patent eligible merely because it has been isolated.").

30. Defendants are engaged in the practice of medicine, not the manufacture of pharmaceuticals.

D. The SVF/ACAM2000 Treatment

31. For Claim Six, the Government must prove: that (1) the SVF/ACAM2000 Treatment involves a drug, (2) the SVF/ACAM2000 Treatment involves a drug that is held for sale in interstate commerce; and (3) the methods used in, or the facilities or controls used for, the manufacture of the drug are not in conformity with current Good Manufacturing Practices ("cGMP"). 21 U.S.C. §§ 331(k), 352(a)(2)(B).

32. For Claim Seven, the Government must prove: (1) that the SVF/ACAM2000 Treatment involves a drug, (2) that the SVF/ACAM2000 Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) that it does not contain adequate directions for use of the symbol "Rx." 21 U.S.C. §§ 352(f), 352(b)(2).

33. Unlike the SVF Surgical Procedure, the SVF/ACAM2000 Treatment constitutes the manufacture of a drug.

34. Because the ACAM2000 was shipped in interstate commerce from Georgia, the Court finds that the SVF/ACAM2000 Treatment satisfies section 331(k)'s "after shipment in interstate commerce" requirement.

35. However, the Government has not met its burden of establishing standing to pursue injunctive relief regarding the SVF/ACAM2000 Treatment because Drs. Berman and Lander stopped performing the treatment by June 2017, before the initiation of this lawsuit and before the seizure of the ACAM2000. Defendants cannot perform the SVF/ACAM2000 Treatment without the ACAM2000, which is in the exclusive control of the Government and otherwise inaccessible to Defendants. Drs. Berman and Lander have no

desire to or intention of performing the SVF/ACAM2000 Treatment absent formal regulatory approval.

E. Attorneys' Fees

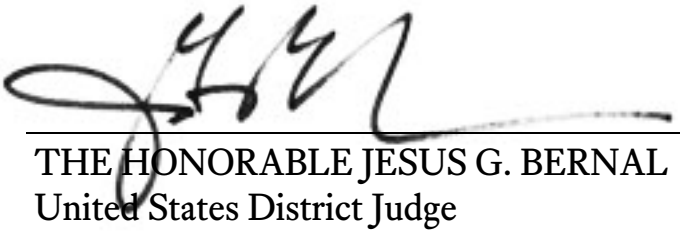
36. The Court declines to award attorneys' fees to Defendants.

37. Congress enacted the Equal Access to Justice Act under 28 U.S.C. § 2412 ("Section 2412") to limit the United States government's immunity to an award for costs and fees. Section 2412 was designed as a gap-filler and applies in the absence of another statute that addresses the issue of attorneys' fees in the case at issue. 28 U.S.C. § 2412(b), (d) ("except as otherwise specifically provided by statute . . ."). Section 2412 is generally applicable whenever the federal government is a party in a civil action. 28 U.S.C. § 2412(d). Given the Government's vast resources and power, Congress determined that parties should be entitled to attorneys' fees where the Government lacks substantial justification for bringing a civil action. Accordingly, Section 2412(d) permits a court to award attorneys' fees and other expenses to a prevailing party unless the Court finds that the Government was "substantially justified." The Supreme Court has concluded that the standard for substantial justification is no different than a "reasonable basis" test. Pierce v. Underwood, 487 U.S. 552, 565 (1988). The Court makes one determination regarding the action as a whole, not to each cause of action. See Ibrahim v. U.S. Dept. of Homeland Sec., 835 F.3d 1048, 1054–57 (2016) (holding that court's decision regarding substantial justification requires a "single inquiry focused on the government's conduct in the case as a whole").

38. Though the Court finds that the SVF Surgical Procedure and Expanded MSC Procedure to not be drugs, and that the SSP Exception unambiguously applies to the SVF Surgical Procedure, other courts have concluded otherwise. See United States v. U.S. Stem Cell Clinic, LLC, 403 F. Supp. 3d

1279 (S.D. Fla. 2019). The Government had a reasonable basis to commence this suit, and accordingly, an award of attorneys' fees is not warranted.

Dated: August 30, 2022



THE HONORABLE JESUS G. BERNAL
United States District Judge